Cl conclude 48. (New) The formulation according to Claim 1, wherein the oil phase is present in an amount ranging from 8 to 10% wt/vol of the final formulation.--

SUPPORT FOR THE AMENDMENT

Support for the amendment to the claims is found in the original claims. Claims 43-48 are new. Support for the newly added claims is found in the original claims. No new matter is believed to be introduced by the above amendment.

REMARKS

Claims 1 and 5-48 are pending. Favorable reconsideration is respectfully requested.

At the outset, Applicants thank Examiner Lukton for his helpful suggestions in overcoming the rejections of the outstanding Office Action.

The rejection of Claims 1-18 and 20-42 under 35 U.S.C. § 112, first and second paragraphs are obviated by the above amendment. Accordingly, withdrawal of these grounds of rejection is respectfully requested.

The rejection of Claims 1 and 2 under 35 U.S.C. § 103 over any combination of Assi, Kurihara, Sekine, Romeo, Ishida, Owen and/or Posanski is believed to be obviated by the above amendment.

The present application relates, in part, to a pharmaceutical composition that overcomes tolerability/toxicity issues that render ramoplanin and its family members impossible to be administered by intraveneous routes. Accordingly, Claim 1 is amended to include the specific embodiments of Claim 2 and 3-4. It should be noted that the Office did not reject Claims 3 and/or 4 over any of the cited references.

Kurihara, Sekine, Romeo, Ishida, and Owen all merely describe methods of

the bioavailability of active drugs. Therefore, these references can not apply to the claimed invention because the claimed invention aims to solve problems for intraveneous delivery. By definition, intraveneous administration renders the active component having 100% bioavailability. Accordingly, the methods described to by Kurihara, Sekine, Romeo, Ishida, and Owen can not apply to the claimed invention.

Assi merely discloses different ramoplanin family members at best. However, Assi clearly fails to disclose the claimed invention because it fails to disclose all of the claim limitations, much less how to administer the family members intraveneously.

Posanski actually teaches away from the claimed invention because it merely teaches how to make therapeutic agents solubilize, and therefore, prepare them for oral administration in aqueous solutions. Accordingly, Posanski fails to disclose or suggest the claimed invention.

None of the above reference along or combined disclose or suggest a composition containing ramoplanin and/or its family members that may be intraveneously administered, much less all of the claim limitations. Further, Claim 1 is amended to include the specific embodiments of Claims 2, 3 and 4. The Office recognizes that the claimed invention is not disclosed or suggested by the cited references because it does not reject Claims 3 or 4 over such references. Accordingly, withdrawal of these grounds of rejection is respectfully submitted.

In addition, Applicants have provided an Abstract in accordance with the Examiner's suggestion. Accordingly, withdrawal of this ground of objection is respectfully requested.

Applicants respectfully submit that the present application is now in condition for allowance. Should anything further be required to place this application in condition for allowance, the Examiner is requested to contact Applicants' attorney by telephone.

Respectfully submitted,

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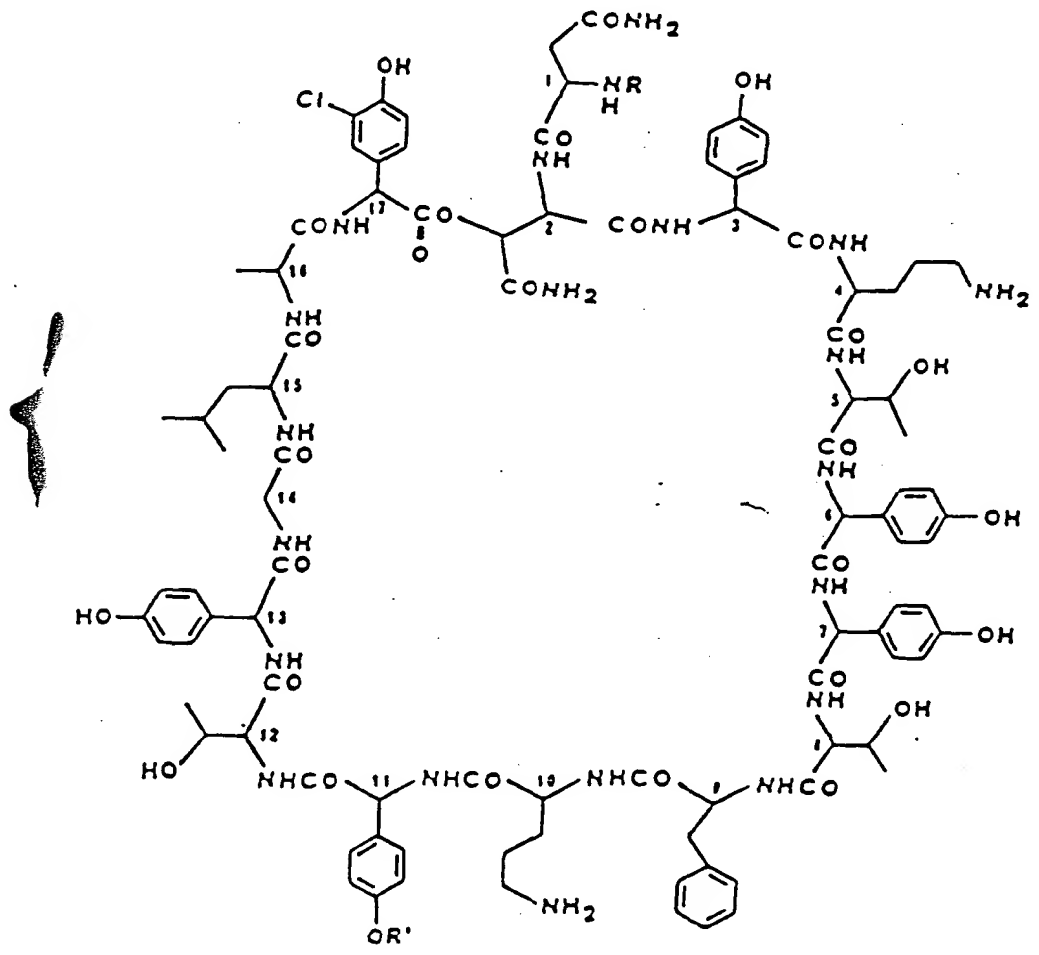
IN THE ABSTRACT OF THE DISCLOSURE

At page 31, after the last line and beginning on the next page, please insert the Abstract of the Disclosure attached hereto.

IN THE CLAIMS

--1. (Amended) A pharmaceutical [Pharmaceutical] formulation for intravenous administration which comprises ramoplanin or a member of the ramoplanin family of formula I



wherein:

R represents -CO-CH=CH-CH=CH-CH_2-CH_2-CH_3,

-CO-CH=CH-CH=CH-CH_2-CH $(CH_3)_2$,

-CO-CH=CH-CH=CH-CH_2-CH_2-CH $(CH_3)_2$,

-CO-CH_2-CH_2-CH_2-CH_2-CH_2-CH_2-CH_3,

-CO-CH_2-CH_2-CH_2-CH_2-CH_2-CH $(CH_3)_2$ or

-CO-CH_2-CH_2-CH_2-CH_2-CH_2-CH_2-CH $(CH_3)_2$

R" represents alpha-D-mannopyranosyl or 2-O-alpha-D-mannopyranosyl-alpha-D-mannopyranosyl, or

R' represents 2,3-0-di[alpha-D-mannopyranosyl]-D-mannopyranosyl and R represents -CO-CH=CH-CH=CH-CH_2-CH $(CH_3)_2$,

a pharmaceutically acceptable acid addition salt thereof, or a mixture thereof in any proportion, in admixture with an amount of fat emulsion product for intravenous administration being a lipid in water microemulsion suitable to be administered by the parental route comprising an oil phase, an emulsifier, and at least one additive as an osmotic agent wherein the concentration of the oil phase is [at least] from 0.2% to 40% (weight/vol) in the final intravenous formulation and comprises at least one vegetal oil consisting of soybean oil, cottonseed oil and sunflower oil which are partially or totally substituted with a mixture of long chain fatty acids in the form of triglycerides having a percent (wt/wt) composition substantially similar to that of the vegetal oil, and the emulsifier is based on at least one phospholipid.

6. (Twice Amended) A formulation according to Claim 1 wherein the oil phase contains long chain fatty acids in the form of triglycerides in the following proportions by

by weight:

linoleic acid 40-70%

oleic acid 15-30%

palmitic acid 5-15%

linoleic acid 3-12%

stearic acid 2-6% wherein the % is wt% based on the total fatty acid content and the total proportions are selected to add up to 100%.

7. (Thrice Amended) A formulation according to claim 1 wherein the fat emulsion product employed for the preparation of said formulation comprises a composition selected from those reported in the following tables:

	Fat emulsion product 1	Fat emulsion product 2	Fat emulsion product 3
Soybean oil (w/vol)	10%	20%	5%
Safflower oil (w/vol)	--	--	5%
Egg yolk phospholipids (w/vol)	1.2%	1.2%	1.2%
Glycerol (w/vol)	2.25%	2.25%	2.5%
Fatty acids composition of vegetable oils (w/vol)			
Linoleic acid	50%	50%	65.8%
Oleic acid	26%	26%	17.7%
Palmitic acid	10%	10%	8.8%
Linolenic acid	9%	9%	4.2%
Stearic acid	3.5%	3.5%	3.4%
Osmolarity (mOsm/L)	260	268	276
Approximate pH	8	8	8

Fat particle size (μm)	0.5	0.5	0.4
Caloric value (cal/ml)	1.1	2.0	1.1
Size (ml)	50, 100	50, 100	25, 50
	250 or	250 or	100, 200
	500	500	Or 500
	Fat emulsion product 4	Fat emulsion product 5	Fat emulsion product 6
Soybean oil (w/vol)	10%	10%	20%
Safflower oil (w/vol)	10%	--	--
Egg yolk phospholipids (w/vol)	1.2%	1.2%	1.2%
Glycerol (w/vol)	2.5%	2.5%	2.5%
Fatty acids composition of vegetable oil (w/vol)			
Linoleic acid	65.8%	54.5%	54.5%
Oleic acid	17.7%	22.4%	22.4%
Palmitic acid	8.8%	10.5%	10.5%
Linolenic acid	4.2%	8.3%	8.3%
Stearic acid	3.4%	4.2%	4.2%
Osmolarity (mOsm/L)	258	284	292
Approximate pH	8.3	8.3	8.3
Fat particle size (μm)	0.4	0.4	0.4
Caloric value (cal/ml)	2.0	1.1	2.0
Size (ml)	25, 50	100, 200	200 or
	200 or	Or 500	550
	500		

and water for injection is from quantum sufficit [quite small] to 100% wherein the above are selected so that the total composition adds up to 100%.

14. (Thrice Amended) A formulation according to claim 1 for treatment of infections caused by [microorganisms] bacteria whose proliferation is inhibited, reduced, alleviated, or arrested in the presence of ramoplanin or [an antibiotic] a member of the ramoplanin family.

15. (Thrice Amended) A method of treating at least one Gram positive [infections] infection, comprising administering the formulation according to claim 1 to a patient in need thereof.

42. (Twice Amended) The method according to Claim 15, wherein the at least one Gram positive [infection] is at least one member selected from the group consisting of bacteremia, endocarditis, and pneumonia.--

--Claims 2-4 are cancelled.--

--Claims 43-48 are new.--